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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,502	02/07/2002	Rolf M. Flugel	012627-022	1264
21839	7590	01/26/2005	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			HILL, MYRON G	
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ALEXANDRIA, VA 22313-1404			PAPER NUMBER	
			1648	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/868,502	FLUGEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Myron G. Hill	1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/3/04</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

This action is in response to paper filed 3 November 2004.

This action is on claims 1- 12 and 17-20.

***Sequence Requirements***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).

Applicant has amended the specification to include reference to SEQ ID#s and the objection is withdrawn.

***Information Disclosure Statement***

A signed and initialed copy of the IDS paper filed 3 November 2004 is enclosed.

***Rejections Withdrawn***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

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The rejection of claim 4 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim 4 has been amended to correct the failure to further limit claim 1.

***Rejections Maintained***

Claim 8 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining a full length FeFV clone, and it does not appear to be readily available material. Deposit of the full length FeFV clone would satisfy the enablement requirements of 35 U.S.C. 112. Applicant's deposit information in the specification does not indicate the extent of public availability.

Applicant argues and shows a copy of the deposit information made under the Budapest Treaty and provides a declaration signed by the Teresa Stanek Rea ( dated 3 November 2004.

Applicant's submissions have been fully considered and not found persuasive.

Applicant has not included the statement required in addition to the Treaty Deposit as set out in the rejection.

Applicant has made a deposit and in paragraph #2 of the declaration makes a statement concerning removal of restrictions. This statement is incomplete because it fails to state that all restrictions imposed by the depositor on the availability to the public

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of the deposited material will be **irrevocably** removed upon the granting of a patent.

The word “irrevocably” is missing from the declaration.

The rejection of record is maintained.

***Rejections Necessitated by Amendment or IDS***

Claims 1, 2, 4- 6, 8-12, and 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector comprising a full length clone of FeFV, does not reasonably provide enablement for vectors containing only a portion of the genome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant argues one of skill in the art could have constructed clones and cites Coffin et al. eds. Retroviruses. Applicant also argues full length clones and replication defective vectors.

Applicant’s arguments have been fully considered and not found persuasive.

The claims do not require the minimal essential elements for a vector. Claim 1 only requires a part of a reverse transcript. Applicants citing of Coffin et al. does not enable all possible viral vectors using FeFV parts of a reverse transcript.

The claims do not require an infectious clone or a replication defective clone. The claims are written in language “comprising” and this is open to other elements

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Applicant is enabled for vectors comprising what is shown in the prior art (Winkler *et al.* or Coffin *et al.*, eds) with the sequence disclosed in the application (which is the same as in Winkler *et al.*) but not any portion comprising a reverse transcript of any FeFV.

The rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

Claims 1-12, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al.* (Journal of Virology 1997, Vol. 71, pages 6727- 6741, from IDS) and Schmidt *et al.* (Virology 1995, Vol. 210, pages 167- 178, from IDS) further in view of Coffin *et al.*, eds, Retroviruses pages 437-441.

The invention is drawn to a retroviral vector comprising at least part of a reverse transcript of the FeFV genome. For this rejection, the claims are interpreted to contain more than the minimum recited elements because of the comprising language.

Applicant argues that Winkler *et al.* does not teach the same clone, does not disclose that the clone can be used to make vectors, and does not disclose a full length clone. And that Winkler *et al.* only states that it would be interesting to examine FeFV as a retroviral vector.

Also, Applicant argues that engineering of an FeFV vector is not possible by simply using the information of Winkler *et al.* because it is needed to have a full length infectious and replication competent clone and that the subgenomic clones are not infectious. Applicant quotes from Winkler *et al.* "repeated attempts to clone" did not

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result in a stable clone. And that Winkler *et al.* does not teach what minimal elements are needed to make a vector.

Lastly, Applicant argues that Schmidt *et al.* fail to overcome the deficiencies.

Applicant's arguments have been fully considered and not found persuasive.

Claim 8 remains in the rejection because it requires the sequence of the clone which is as disclosed in Winkler *et al.* and does not claim the clone itself.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's arguments about full length infectious clones are not commensurate in scope with the claims because the claims only require a retroviral vector.

Applicant also asserts that the fragment that did not clone was a full length clone. It was in fact only a 4.7Kb fragment and that fragment was able to be cloned in parts. See next sentence from quoted passage.

Winkler *et al.* did obtain the full sequence of FeFV and identified all the parts. Winkler *et al.* did show that the genome ends and the transactivator functioned (Tables 1 and 2).

One of ordinary skill in the art at the time of invention would know about construction of retroviral vectors and could use the detailed information in Winkler *et al.* to construct FeFV vectors. It is well known in the art that retroviral vectors are used to

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express or deliver foreign genes. One of ordinary skill in the art would be motivated to make a FeFV retroviral vector to study foamy viruses as vectors as taught by Winkler *et al.* (page 6727, last paragraph of introduction). Knowing the full length sequence and having the partial clones of Winkler *et al.* it would have been obvious to make a plasmid that contains a full length proviral clone. The knowledge of what is required to make a retroviral clone is discussed in Schmidt *et al.* and is known in the art as discussed by Coffin *et al.*, eds. Retroviruses (cited by Applicant in IDS in paper that this action is responsive to).

The rejection is maintained.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill  
Patent Examiner  
21 January 2005

